DIMA	510K SUMMARY	ANCHORSURE	K120831

OCT 12 2012

SUBMITTER:	Neomedic International, S.L. C/ Maestrat 41-43 1° 08225 Terrassa (Barcelona) Spain
CONTACT PERSON:	Jeffrey Shideman, Ph.D.
DATE PREPARED:	October 10th 2012
DEVICE NAME:	ANCHORSURE
REGULATION NUMBER:	21 CFR 884.4530
REGULATION NAME:	Obstetric-gynecologic specialized manual instrument
PRODUCT CODE:	PBQ
PREDICATE DEVICES:	GYNECARE PROLENE FASTENER SYSTEM (K042603)

Device Description:

Anchorsure is a suture kit that consists of monofilament polypropylene suture, an anchor, an anchoring handle, and a surgical needle.

Description of material components and physical properties:

Component	Material
Suture	Polypropylene monofilament
Anchor	PEEK
Anchoring Handle	Stainless steel AISI 303 POM
Surgical Needle	Stainless steel

Component	Properties
Monofilament polypropylene suture	USP 0 Diameter: 0.4 mm Length: 800 mm
Anchor	Diameter: 3 mm Length: 7 mm
Anchoring Handle	Anchoring Handle tube diameter = 6 mm Anchoring Handle tube length = 204 mm
Surgical Needle	Diameter: 1,1 mm Curved diameter: 20 mm

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Predicate Devices:

The following device has been previously cleared by the FDA in the following 510(K):

Device	510 (K) document number	Date Cleared	Indications
GYNECARE PROLENE FASTENER SYSTEM	K042603	December 22nd 2004	Suture kit

Intended Use:

Anchorsure is indicated for attaching suture to ligaments of the pelvic floor.

Technological Characteristics:

Anchorsure and the Gynecare Prolene Fastener do not have the same technological characteristics because Anchorsure is a suture kit and the Gynecare Prolene Fastener is a staple. The new technological characteristics of the Anchorsure could affect safety and effectiveness. However, the new characteristics do not raise new issues of safety and effectiveness because both devices are used to attachment ligaments to the pelvic floor. Accepted scientific methods exist to assess the effects of the new characteristics – specifically those described in the "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" issued on June 3, 2003.

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Performance tests:

Performance test	Test description
Sterilization	Ethylene oxide residuals Ethylene chlorohydrins residuals Sterility assurance level (SAL) determination
Packaging	Accelerated Aging Study
Biocompatibility	Biocompatibility testing completed on the Surelift Prolapse System (K102815) was used to support the biocompatibility of Anchorsure.
Mechanical tests	Suture strength evaluated per USP 881. Anchor strength Suture diameter evaluated per USP 861. Pullout strength of the anchor Tensile strength of the suture-anchor interface evaluated per USP 871

Results of verification testing indicate that the product meets the established performance requirements and standards.

Conclusions:

Anchorsure is substantially equivalent to its proposed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neomedic International S.L.
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OCT 12 2012

Re: K120831
Trade/Device Name: ANCHORSURE
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: PBQ
Dated: September 6, 2012
Received: September 10, 2012

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120831

Device Name: ANCHORSURE

Indications for Use:

Anchorsure is indicated for attaching suture to ligaments of the pelvic floor

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120831